

UNITED STATES BANKRUPTCY COURT
DISTRICT OF DELAWARE

In re :
VIVUS, INC., *et al.*,
Debtors.

Chapter 11
Case No. 20-11779 (LSS)
(Jointly Administered)
Related Docket Nos. 13, 141, 143, 144, 145

**OMNIBUS REPLY IN SUPPORT OF THE DEBTORS'
JOINT PREPACKAGED CHAPTER 11 PLAN OF REORGANIZATION
OF VIVUS, INC. AND ITS AFFILIATED DEBTORS**

IEH Biopharma LLC (“IEH”), the Supporting Noteholder¹ and Exit Facility Lender under the Plan, submits this memorandum of law in support of the Plan and in response to the (i) *Objection of Steven Chlavin to Confirmation of the Joint Prepackaged Chapter 11 Plan of Reorganization of Vivus, Inc. and its Affiliated Debtors* [Docket No. 138] (the “**Chlavin Objection**”), (ii) *Objection to Confirmation of Plan* filed by Bruce Makosky [Docket No. 144] (the “**Makosky Objection**”), (iii) *Objection to Confirmation of Plan* filed by Vasilios Manousiouthakis [Docket No. 143] (the “**Manousiouthakis Objection**”), (iv) *Objection to Confirmation of Plan* filed by Dennis Dijkstra [Docket No. 145] (the “**Dijkstra Objection**” and together with the Chlavin Objection, Makosky Objection and Manousiouthakis Objection, the “**Shareholder Objections**”) and (v) *United States Trustee’s Objection to Confirmation of Joint Prepackaged Chapter 11 Plan of Reorganization of Vivus, Inc. and its Affiliated Debtors* [Docket No. 141] (the “**UST Objection**”, and together with the Shareholder Objections, the “**Objections**”). IEH also reserves the right to join in the arguments set forth in the Debtors’ brief in support of confirmation.

¹ Capitalized terms not defined herein shall have the meaning ascribed in the *Joint Prepackaged Chapter 11 Plan of Reorganization of Vivus Inc. and Its Affiliated Debtors* [Docket No. 13] (the “**Plan**”).

PRELIMINARY STATEMENT

1. The Debtors' Plan is the product of extensive good-faith, arm's-length negotiations with IEH that began well before the Debtors commenced these chapter 11 cases. As set forth in further detail below, in the many months preceding this bankruptcy filing, the Debtors on three separate occasions sought to raise additional debt and equity financing to repay the maturing Convertible Notes. The Debtors' refinancing efforts were consistently supported by IEH up through the filing of these chapter 11 cases, including as set forth in the Restructuring Support Agreement (as amended, the "RSA"). Unfortunately, the Debtors were not successful in raising sufficient funds to repay the Convertible Notes, which are now matured.

2. In accordance with the RSA and the Plan, all of the Debtors' creditors, other than IEH, will receive payment in full of their claims. In addition, even though they are not entitled to any recovery, IEH has agreed to provide substantial consideration to the Debtors' shareholders in exchange for such shareholders satisfying the Existing Stock Settlement Conditions, including by agreeing to provide the third party releases. Such releases are thoroughly described in the Plan, the Disclosure Statement and in the opt-out notices, all of which were sent to all of the Debtors' shareholders.

3. Notwithstanding the financial realities confronted by the Debtors and the distributions provided to the Debtors' stakeholders under the Plan, the Debtors received the Objections which primarily raise two issues: (1) whether the Debtors' valuation should be approved, as raised in the Shareholder Objections and (2) whether the proposed third party releases and opt-out mechanics for the Existing Stock Settlement are appropriate, as addressed in the US Trustee Objection. For the reasons set forth below, each of the Objections should be overruled and the Plan should be confirmed.

4. With respect to the Shareholder Objections, each of the shareholders offer

speculation and conjecture in an attempt to convince this Court that they are entitled to distributions under the Plan and to retain their equity interests in the Debtors. This is wrong for several reasons: First, the Debtors' have met their burden to show that the enterprise value of the Debtors is no more than \$225 million (inclusive of VI-0106 and tax attributes) and the shareholders have not introduced any credible opposition thereto.² Second, prior to the Petition Date the Debtors' actively sought to raise debt and equity financing in an amount sufficient to repay the Convertible Notes. At best, the Debtors would have been able to raise approximately \$197 million which was insufficient. Accordingly, the capital markets have valued the Debtors at an amount lower than the low end of the Debtors' enterprise value range. Third, the Shareholder Objections have not proposed how the Debtors could satisfy all of their debt obligations going forward without the equitization of the Convertible Notes and reinstatement of the Secured Notes in the proposed Exit Facility. Accordingly, the Shareholder Objections should be overruled and the Plan should be confirmed.

5. With respect to the U.S. Trustee Objection, the U.S. Trustee objects to, among other things, the proposed releases under the Plan. The Plan is the Debtors' only viable option to address their substantial debt burden and concluding these chapter 11 cases in an expeditious manner that preserves the Debtors' operations as a going concern, pays all of the Debtors' creditors, other than IEH, in full and provides a recovery to equity holders that participate in the Existing Stock Settlement with a meaningful recovery that they are not otherwise entitled to as a matter of law. All shareholders were provided with notice and an opportunity to opt-out of the Existing Stock Settlement.³ Absent participation in the Existing Stock Settlement, including the granting of the

² Disclosure Statement, pp. 75, 89 and Ex. F p. 2.

³ It is IEH's understanding that only a small number of the Debtors' shareholders opted out of the releases and Existing Stock Settlement.

third party releases, IEH would not provide the consideration for shareholders set forth in the Plan. The releases, from any party, are also integral to the Plan more generally. The implied value of the Plan well exceeds the Debtors' enterprise value. IEH is willing to provide that value in order to facilitate the Debtors' smooth exit from bankruptcy so as to minimize the impact on their business, which, by definition, requires that any potential disputes also be resolved. Accordingly, the U.S. Trustee Objection should be overruled in accordance with the applicable law in this district.

BACKGROUND

6. Since October 7, 2015 (five years before the bankruptcy filing), IEH has held approximately \$170 million of the Debtors' Convertible Notes. In the fall of 2019, the Debtors reached out to IEH to advise that they had insufficient cash on hand to pay the Convertible Notes in full and would seek to refinance the Convertible Notes. IEH was supportive of the Debtors' refinancing efforts. As a case in point, during the Debtors' August 6, 2019 and November 5, 2019 earnings calls, the Debtors noted the upcoming maturity date under the Convertible Notes but mentioned that the Convertible Notes were not callable and that, therefore, it did not make sense to refinance or pay the Convertible Notes until closer to the maturity date to avoid paying "double interest."⁴ Hearing this, in the fall of 2019, IEH offered to waive any prohibition on redemption prior to the maturity date without any related fee to eliminate any payment of double interest in the event the Convertible Notes were refinanced.

7. Shortly thereafter, beginning in late 2019, the Debtors began to canvas the market for sources of new capital. Disclosure Statement, p. 24. The Debtors received several offers from

⁴ Vivus August 6, 2019 Earnings Call, p. 5, <https://www.sec.gov/Archives/edgar/data/881524/000110465919045101/0001104659-19-045101-index.htm>; Vivus November 5, 2019 Earnings Call, p. 11, https://www.sec.gov/Archives/edgar/data/881524/000110465919061682/a19-22314_1ex99d1.htm.

interested parties, engaged in productive negotiations with various financing sources and expected to close a refinancing transaction by April 2020. *Id.* Unfortunately, in March 2020, the refinancing the Debtors had been working on disintegrated. *Id.*

8. “With the Convertible Note Maturity Date still looming and insufficient cash on hand to pay the outstanding Convertible Note[s] in full, the Company accelerated its contingency planning and contemplated filing for chapter 11 protection. During this time, the Company entered into active discussions with IEH, as the holder of approximately \$170.1 million of the \$181.6 million outstanding principal amount of Convertible Note[s] set to mature on the Convertible Note Maturity Date.” *Id.* In April 2020, the Debtors approached IEH to request a grace period on repayment of the Convertible Notes while they again tried to refinance the Convertible Notes, but with a contingency plan that IEH would take ownership through bankruptcy if the refinancing did not occur. On April 29, 2020, the Debtors and IEH entered into that certain Agreement Regarding Convertible Notes (the “**Forbearance Agreement**”), which was filed with the SEC on May 1, 2020.⁵ Pursuant to the Forbearance Agreement, IEH provided the Debtors with forbearance through June 1, 2020,⁶ which was later extended to July 13, 2020 under the RSA, without payment of any fee.⁷ To facilitate the Debtors’ chapter 11 contingency planning and so that the forbearance could be effectuated, IEH permitted all other Convertible Noteholders to be paid or otherwise satisfied on the maturity date of the Convertible Notes.⁸ This “provide[d] the Debtors with 62 days of forbearance to continue their prepetition efforts to refinance the Convertible Notes while the Debtors and IEH concurrently negotiated the Plan as a contingency.” *Id.*

⁵ Forbearance Agreement, <https://www.sec.gov/Archives/edgar/data/881524/000110465920055004/0001104659-20-055004-index.htm>.

⁶ *Id.* at 2.

⁷ RSA, p. 1, <https://www.sec.gov/Archives/edgar/data/881524/000110465920068654/0001104659-20-068654-index.htm>

⁸ Forbearance Agreement, pp. 2, 4.

9. During the forbearance period, the Debtors again tried twice to refinance the Convertible Note with IEH's consent (*id.*), later documented in the RSA entered into on May 31, 2020. *See RSA*, pp. 7-8, 12, Ex. B to the Disclosure Statement. Notably, the RSA was the subject of an 8-K filed on June 2, 2020, which expressly stated that:

- a. The Debtors could refinance the Convertible Notes, but if the refinancing did not occur by June 30, 2020 the parties would work towards a pre-negotiated restructuring in bankruptcy to be filed on or before July 13, 2020;⁹
- b. The Convertible Notes would be converted to 100% of the equity in the reorganized Debtors through the bankruptcy restructuring;¹⁰ and
- c. Shareholders would receive no distribution, but each would be entitled to participate in a settlement, should they so choose, providing recovery up to \$2.28¹¹ per share (which stock was trading at \$1.12 per share at the time).¹²

10. On or about June 30, 2020, the Debtors advised IEH that a refinancing was unlikely to occur and that bankruptcy was the Debtors' best option. In the days that followed, the Debtors and IEH focused on finalizing a consensual restructuring, which required two things. First, “[o]n July 2, 2020, . . . IEH acquired 100% of the outstanding Secured Notes from Athyrium with the Debtors' consent,” which “facilitate[d] a 'ride-through' prepackaged Plan that would significantly streamline the Restructuring” and minimize business disruption (Disclosure Statement, pp. 19-20, 25), as opposed to the pre-negotiated bankruptcy contemplated in the RSA. Second, “[o]n July 6, 2020 the Debtors and [IEH] entered into an amended RSA which provides the terms of the Plan

⁹ June 2, 2020 8-k, p. 2, <https://www.sec.gov/Archives/edgar/data/881524/000110465920068654/0001104659-20-068654-index.htm> (“If the Company is unable to complete the Permitted Refinancing by [June 30, 2020], the Company will pursue a restructuring of the Company pursuant to a plan of reorganization . . . and the Company will file petitions for voluntary relief under chapter 11 . . . on or before July 13, 2020 (the ‘Petition Date’).”).

¹⁰ *Id.* at 3 (“claims under the Convertible Notes Indenture . . . will be exchanged for 100% of the equity”).

¹¹ The Contingent Value Agreement has been filed with the Court [Docket No. 100], so there are no unknown contingencies in respect of shareholder recovery as Mr. Dijkstra postulates. *See* Dijkstra Motion, p. 4.

¹² *Id.* at 4 (“all interests will be disallowed and will be cancelled under the Plan; however, pursuant to a settlement . . . [a] holder may receive . . . its pro rata share of \$5 million and a non-transferrable contractual contingent value right to earn another \$2 per share. . . .”); VIVUS stock price historical data, <https://www.otcmarkets.com/stock/VVUSQ/overview> (all stock prices are available on the OTC site, and so are not cited throughout).

as a prepackaged plan.” *Id.* at 28. The proposed treatment of shareholders was not modified in the RSA. On the following day, July 7, 2020, the Debtors filed for bankruptcy.

STATEMENT IN SUPPORT OF PLAN

11. To obtain confirmation of a chapter 11 plan, the proponent must demonstrate, among other things, that the plan satisfies each of the requirements set forth in section 1129 of the Bankruptcy Code. *See In re Lackawanna Detective Agency, Inc.*, 82 B.R. 336, 337 (Bankr. D. Del. 1988) (“Section 1129(a) of title 11 recites the standards which must be met before a plan can be confirmed.”); *In re Richard Buick, Inc.*, 126 B.R. 840, 846 (Bankr. E.D. Pa. 1991). The Plan satisfies such requirements by a preponderance of the evidence and should be confirmed. *See In re Armstrong World Indus., Inc.*, 348 B.R. 111, 120 (D. Del. 2006) (“[T]he debtor's standard of proof that the requirements of [section] 1129 are satisfied is preponderance of the evidence.”).

12. The Debtors’ Plan, which was proposed in good faith, allows the Debtors to maintain all business relationships with vendors, pays all secured and unsecured creditors in full, other than IEH, and provides a meaningful distribution to the Debtors’ shareholders who satisfy the Existing Stock Settlement Conditions. The Plan allows the Debtors to emerge from bankruptcy with a substantially reduced balance sheet in accordance with its enterprise value. Therefore, there can be no doubt that confirmation of the Plan is in the best interest of the Debtors and their creditors.

RESPONSE TO OBJECTIONS

A. The U.S. Trustee Objection Should be Overruled

i. The Plan Releases are Appropriate and Should be Approved

13. The U.S. Trustee argues that the Plan releases are inconsistent with bankruptcy law and should not be approved. For the following reasons, the U.S. Trustee’s contentions are without merit.

a. The Releases are Part of a Plan Settlement

14. The releases are part of a Plan settlement negotiated at arms' length, and in good faith. The Bankruptcy Code authorizes the Debtors to settle or adjust "any claim or interest belonging to the debtor or to the estate" pursuant to a plan. 11 U.S.C. § 1123(b)(3). Plan settlements implemented through Bankruptcy Code section 1123 are evaluated under Bankruptcy Rule 9019. *See e.g., In re Nutritional Sourcing Corp.*, 398 B.R. 816, 832 (Bankr. D. Del. 2008); *In re Coram Healthcare*, 315 B.R. 321, 329-30 (Bankr. D. Del. 2004) (evaluating plan settlement under Bankruptcy Rule 9019). Indeed, "[c]ompromises are favored in bankruptcy." *Myers v. Martin (In re Martin)*, 91F.3d 389, 393 (3d Cir. 1996) (citation omitted). Even if the Court determines that Bankruptcy Rule 9019 does not apply, the equity settlement should be evaluated under the fair and equitable standard set forth in section 1129(b)(1) of the Bankruptcy Code.

15. The releases are part of a settlement negotiated by and between the Debtors and their independent directors and IEH. To the extent any shareholder does not want to participate in the settlement and forego its distributions under the Plan, they only need to opt-out of the Existing Stock Settlement. By utilizing the opt-out structure the Debtors' have ensured the greatest number of shareholders receive the consideration being provided under the Existing Stock Settlement, and that those that do not want to participate in the Existing Stock Settlement need only complete and return a form as opposed to objecting to the Plan. Indeed, the efficacy of the opt-out mechanism is demonstrated by the small number of shareholders that exercised their opt-out right.

b. The Releases are Consensual

16. The releases are consensual and should be approved accordingly. The majority view in this district is that third party releases are both consensual and appropriate where holders of claims and/or interests are provided with the informed opportunity to opt-out of such releases, but take no such action. *See, e.g., In re Pace Indus., LLC*, Case No. 20-10927 (MFW) (Bankr. D.

Del. May 29, 2020) [Docket No. 215] (approving plan releases and finding them consensual where creditors were required to file objections to the releases to opt-out); *In re Insys Therapeutics*, Case No. 19-11292 (KG) (Bankr. D. Del. Jan. 16, 2020) Hr'g Tr. 110:23-25; 111:1-3 (overruling objection and confirming a plan with third-party releases that included as releasing parties all holders deemed to reject the that did not opt-out of granting the releases); *In re Triangle Petroleum Corp.*, Case No. 19-11025 (MFW) (Bankr. D. Del. June 14, 2019) [Docket No. 71] (approving third party releases with respect to holders of claims that voted to reject or abstained from voting on the plan but failed to opt-out of granting such releases); *In re Z Gallerie, LLC*, Case No. 19-10488 (LSS) (Bankr. D. Del. June 13, 2019) Hr'g Tr. 48:9-11 (“With respect to third-party releases I’m prepared to find that they are consensual because of the opt-out box in the ballots.”); *In re Southeastern Grocers, LLC*, Case No. 18-10700 (MFW) (Bankr. D. Del. May 30, 2019) Hr'g Trans. at 37:1-25 (concluding that releases were consensual because unimpaired claimants received notice and were afforded the opportunity to file an objection to the release, thus constituting consent); *In re Checkout Holding Corp.*, Case No. 18-12794 (KG) (Bankr. Del. Jan. 31, 2019) [Docket No. 266] (releases by creditors found to be consensual if they did not vote on the plan or voted to reject the plan but did not check the opt-out box); *In re David’s Bridal, Inc.*, Case No. 18- 12635 (LSS) (Bankr. Del. Jan. 4, 2019) [Docket No. 279] (same); *In re EV Energy Partners*, Case No. 18-10814 (CSS) (Bankr. D. Del. Aug. 28, 2018) Hr'g Trans. at 212:1-25; 214:6-25 – 215:1 (finding that those claimants in classes deemed to reject received notice and an opportunity to object); *In re Remington Outdoor Co., Inc.*, Case No. 18-10684 (BLS) (Bankr. D. Del. May 2, 2018), Hr'g Trans. at 72:14-25; 73:1-6 (finding the releases appropriate for (i) unimpaired claims (deemed to accept) and (ii) those claimants voting to reject the plan or abstaining from voting who failed to check the opt-out box on the ballot); *In re TK Holdings Inc.*,

et al., Case No. 17-11375 (BLS) (Bankr. D. Del. Feb. 14, 2018) [Docket No. 2050] (order confirming plan and approving third party releases by creditors who had consented by not opting out of the release, either by abstaining from voting or by voting against the plan without affirmatively electing to opt-out).

17. The U.S. Trustee points to Judge Owens' opinion from last year in *Emerge Energy Services LP*, Case No. 19-11563 (KBO), 2019 WL 7634308, *18 (Bankr. D. Del. Dec. 5, 2019), for the purported proposition that silence may not be construed as consent to a plan release. The foregoing is, by Judge Owens' own statement, the minority position in this district. *Id.* ("The Court understands that its position is a minority amongst the judges of this District."). Even so, Judge Owens found the third-party releases to be non-consensual as to equity holders who were not receiving a distribution under the Plan. *See, e.g., Emerge Energy*, 2019 WL 7634308, at *18 (finding third-party releases to be non-consensual as to equity holders who were "receiving no distribution under the Plan and [where] no previous dealings between the parties [were] in evidence."). Such is not the case here, as the holders of existing stock are receiving ample consideration, in the form of the Existing Stock Settlement.

18. Further, the *Emerge Energy* court's reliance on contract principles to determine who a plan can bind is misplaced. While nonbankruptcy concepts can provide guidance in bankruptcy matters, a chapter 11 plan of reorganization operates as a creature distinctly unique to bankruptcy matters. Often referred to as a "super contract," a plan can bind nonsignatories. *See In re Montgomery Ward Holdings Corp.*, 306 B.R. 489, 495 (Bankr. D. Del. 2004) (a confirmed plan is "a legally binding agreement"). Relying on state law contract principles to evaluate consent to a third party release is improper. *See In re Frontier Ins. Grp., Inc.*, 585 B.R. 685, 693 (Bankr. S.D.N.Y. 2018) ("References to chapter 11 plans as contracts or agreements—while useful for

purposes of interpreting plans . . .—are only by analogy, however. The binding effect of a chapter 11 plan is in fact premised on statutory and common law claim preclusion.”), aff’d, 598 B.R. 87 (S.D.N.Y. 2019). Rather, section 1141 (a) of the Bankruptcy Code binds holders of claims and interests to a plan’s provisions—including third-party releases contained therein—if such party in interest receives proper notice but fails to object to confirmation of the plan. *See* 11 U.S.C. § 1141(a) (providing that a confirmed plan binds, among others, “any creditor . . . whether or not the claim or interest of such creditor . . . is impaired under the plan . . .”).

19. The 2018 decision, *In re Tops Holding II Corp.*, is poignant. Case No. 18-22279 (RDD) (Bankr. S.D.N.Y. Nov. 9, 2018). During the confirmation hearing, the court explained that the Bankruptcy Code governs the issue of consent: “So I believe those two cases [*Chassix* and *SunEdison*] clearly do not stand for the general proposition, which would be inconsistent with substantial circuit level case law, including in the Second Circuit, as well as Section 1141, 1141(a)’s and (c)’s plain language, that a plan is binding, if one does not object, let alone if one does not opt-out.” *Id.* [Docket No. 783] Confirmation Hr’g Tr. 73:8-13. In that case, Judge Drain determined that section 1141(a) of the Bankruptcy Code provided “the source for the deemed consent,” and held that a similar opt-out mechanism was sufficient to imply consent. *Id.* at 39:18–19.

20. IEH submits that section 1141 of the Bankruptcy Code binds parties to a plan, and as such, in this case, equity holders, must affirmatively object to release provisions, as they would any other plan provision. Indeed, the foregoing is a position recently echoed by this Court. In *In re Melinta Therapeutics*, this court said “I haven’t yet heard, and it’s probably because it’s more of an emerging [area of] case law, a real response to the 1141 argument, but as I said during our argument here, it’s compelling to me and more compelling than the contractual argument. So, until

I hear a real response to the 1141 argument, that is where my thinking is; that 1141 binds creditors to a plan and creditors need to, therefore, speak up and object to release provisions, like they need to other provisions.” Case No. 19-12748 (LSS) [Docket No. 502] (Bankr. D. Del. Apr. 6, 2020) Confirmation Hr’g Tr. 120:6–14. Accordingly, IEH submits that this Court should apply the majority position in this district and the plain language of section 1141, and approve the releases as consensual.

c. Alternatively, the Releases Should be Approved under the Continental Framework

21. Even if this Court were to decide that the releases were nonconsensual, they should still be approved. Nonconsensual third party releases are permissible in the Third Circuit. *In re Continental Airlines, Inc.*, 203 F.3d 203, 214 (3d Cir. 2000); *see also In re Millennium Lab Holdings II, LLC*, 945 F.3d 126, 139-40 (3d Cir. 2019). “The hallmarks of permissible non-consensual releases [are] fairness, necessity to the reorganization, and specific factual findings to support these conclusions[.]” *In re Continental Airlines, Inc.*, 203 F.3d at 214.

22. The releases are both fair within the context of the Plan, and strictly necessary to the Debtors’ reorganization. The Plan is premised upon the RSA and provides for an integrated settlement comprised of the payment in full of all of the Debtors’ secured and unsecured creditors, other than IEH, and a meaningful distribution to shareholders that participate in the Existing Stock Settlement, even though shareholders are not entitled to any distributions under the Plan as a matter of law.

23. Additionally, the Debtors disclosed the terms and conditions of the releases, including the opt-out mechanism and proposed treatment of interests, through both postpetition opt-out notices and multiple SEC filings prior to the Petition Date. Indeed, IEH understands that a small number of shareholders have opted-out of the Existing Stock Settlement and releases and

four shareholders have objected to the Plan. As such, it is clear that the terms of the releases did nothing to impede shareholder decision making and that the substantial majority of shareholders who did not elect to opt-out of the Existing Stock Settlement should receive the value being offered to them.

B. The Shareholder Objections Should be Overruled

i. The Shareholders' Purported Valuations Are Baseless

24. The Shareholder Objections argue that Piper Sandler & Co.'s ("Piper Sandler") valuation¹³ is too low, but they offer only the same speculation and conjecture that they included in their requests for appointment of an equity committee. The objecting shareholders make two primary arguments: (1) that the valuation fails to value VI-0106; and (2) that it fails to value the Debtors' NOLs. These arguments are without merit.

a. VI-0106 Provides No Basis for an Increase in Valuation

25. The Shareholder Objections argue that VI-0106 makes the Debtors' solvency apparent. *See* Chlavin Obj. ¶ 7; Dijkstra Obj. pp. 4-6; Makosky pp. 10-11; Manousiouthakis p. 1. VI-0106 is still in research and clinical development, and has not passed phase 2 or phase 3 clinical trials.¹⁴ The Debtors have been clear that any potential revenue from VI-0106 is still years away and that they "may not be able to successfully develop, launch and commercialize VI-0106" for at least the following reasons:

- The Debtors may not "successfully develop a proprietary formulation" such that there is never any proprietary treatment to commercialize;
- Any development will take years (as the Debtors need to "conduct phase 2 and phase 3 clinical testing on tacrolimus, which could be delayed by slow patient

¹³ Mr. Dijkstra argues that Piper Sandler has a "conflict of interest" because in two instances that Mr. Dijkstra, admits are "unrelated to this case," Dentons and Piper Sandler have been involved in bankruptcy cases together. There are of course a finite number of investment banks and law firms with restructuring practices, and the simple fact that both have been involved in two unrelated cases is not any indication of a conflict.

¹⁴ 2019 10-k, p. 9 <https://www.sec.gov/Archives/edgar/data/881524/000155837020001956/vvus-20191231x10k.htm#Item8FinancialStatementsandSupplementary>.

enrollment, long treatment time required to demonstrate effectiveness, disruption of operations at clinical trial sites, adverse medical events or side effects in treated patients, failure of patients taking the placebo to continue to participate in the clinical trials, and insufficient clinical trial data to support effectiveness of VI-0106”);

- The Debtors would then still need to “obtain regulatory approval and market authorization” to commercialize VI-0106; and
- VI-0106 may never be commercially viable as the Debtors may never “achieve market acceptance by patients, the medical community and third-party payors and generate product sales. . . .”¹⁵

Most importantly, the ***Debtors’ SEC filings have been explicit that they don’t have sufficient funds to launch, develop, or commercialize VI-0106*** -- they have tried, but been unable to, secure “alternatives for financing the development of tacrolimus.”¹⁶

26. Teri Stratton, Managing Director at Piper Sandler, noted that these facts played into her analysis of the value of VI-0106:

It is my understanding that the company has not initiated any trials with VI-0106. It is -- it is also my understanding that it would cost approximately \$40 million to get to commercialization, and that it could take several years.

...

[T]here are about a dozen therapies that are currently used for PAH patients today, for pulmonary arterial hypertension, and there are about 12 or 13 competing develop -- projects in development, and that some of those are further along in development than the VI-0106; and that, even if they could get to commercialization fast, it may be that, at the time they get there, it is not a competitive product. [Aug. 7, 2020 Hearing Tr. at 65:5-66:2.]

27. Indeed, the Vivus presentation attached to Mr. Dijkstra’s Objection notes that as of September 2019, the Debtors’ philosophy in “evaluating additional in-licensing and acquisition

¹⁵ *Id.* at 37.

¹⁶ *Id.* at 8.

candidates" required that the products "have some market barriers to entry" and "have a significant clinical following and are important in the treatment of the medical condition(s) for which the product is indicated." Dijkstra Obj. p. 27. VI-0106 lacks these elements.

28. Ignoring these facts, Messrs. Manousiouthakis and Makosky boldly assert that "Vivus can easily secure at least \$90 million of funding by licensing VI-0106." *See* Manousiouthakis Obj. p. 1; *see also* Makosky Obj. p. 10.¹⁷ Mr. Makosky, via Mr. Ahmadi, points to a press release from MannKind Corporation, purportedly stating "United Therapeutics had obtained an exclusive license of the PAH drug Treprostinil Technosphere for \$95 million in upfront and milestone payments." (Makosky Obj. p. 10; *see also* Manousiouthakis Obj. p. 1.)¹⁸ Here, the Debtors have already gone to market to find equity and debt financing for all of the Debtors' assets, including, VI-0106 and were unsuccessful in obtaining an amount of financing necessary to satisfy debt obligations. There is, therefore, no value of the Debtors' assets in excess of their debt.

29. Mr. Ahmadi further speculates that "VI-0106 has . . . a value of about \$1.2 billion, following successful completion of phase 2 trials within a year," despite no evidence that such a successful completion is likely ever, let alone within that timeframe. Makosky Obj. p. 10. Again Mr. Ahmadi bases his analysis on the licensing of a different drug to United Therapeutics by a different company, Arena. *Id.* The article Mr. Ahmadi cites indicates that Arena completed its

¹⁷ Mr. Manousiouthakis also suggests that the Court should "order that Vivus immediately and openly solicit offers in the marketplace for VI-0106." (Manousiouthakis Obj. p. 1.) However, given that under the Plan IEH is not being paid on the secured notes it holds, and is reducing the amount it will be paid on its convertible notes by 24%, it cannot also be required to permit the sale of VI-0106.

¹⁸ Mr. Ahmadi glosses over the contingent nature of the majority of these payments to MannKind and does not take into account any factors relevant to the Debtors. Specifically, (a) up to \$50 million of the proposed financing is dependent upon the achievement of specific development targets, (b) included for this price was an option to license other MannKind products, (c) the agreement was coupled with "a research agreement for the conduct of research by MannKind on behalf of United Therapeutics for products outside the scope of the licensing and collaboration agreement," and (d) there is no indication that MannKind faced any of the same hurdles detailed above that Vivus faces regarding VI-0106.

phase 2 trials nearly two years ago (while Debtors have still not completed phase 2 trials), and that the resulting data (which the Debtors don't have) was "well-regarded."¹⁹ Arena's situation is in no way comparable to that of the Debtors'. *See also* Aug. 7, 2020 Hearing Tr. at 56:4-23.

30. The Shareholder Objections and the views of Mr. Ahmadi present no justifiable methodology to support their valuation claims as is required in this district. There are three valuation methodologies utilized under standard valuation practices. *In re Nellson Nutraceutical Inc.*, 356 B.R. 364, 370 (Bankr. D. Del. 2006) (finding standard methodologies to include (i) a discounted cash flow analysis, (ii) a precedent transaction or comparable transaction analysis, and (iii) a publicly traded company or comparable company analysis). Mr. Ahmadi did not use any of these methodologies. In reality, VI-0106 is a speculative and costly treatment that is, at best, years away from producing revenue; and, even if the Debtors had funding to bring VI-0106 to market it may not be profitable. The objecting shareholders' speculative valuations based on faulty comparisons and without the use of any recognized valuation methodologies should be disregarded and viewed with a net present value of zero, as determined by Ms. Stratton and as other courts often do when confronted with assertions of speculative value. *In re Spansion*, 421 B.R. at 163; *In re Ampex Corp.*, Case No. 08-11094 (AJG), 2008 WL 2051128, at *2 (Bankr. S.D.N.Y. May 14, 2008).

b. The NOLs Provide No Basis for an Increase in Valuation

31. The Shareholder Objections misunderstand the value of the NOLs. Messrs. Manousiouthakis and Makosky argue that Debtors' NOLs are "worth \$238 million" (Manousiouthakis Obj. p. 1) or "at least \$235.5 million." Makosky Obj. p. 11. Mr.

¹⁹ Phil Taylor, *Arena bags big deal with United for PAH drug ralinepag*, Fierce Biotech (Nov. 15, 2018), <https://www.fiercebiotech.com/biotech/arena-bags-big-deal-united-for-pah-drug-ralinepag>

Manousiouthakis provides no support for his figure, while Mr. Makosky's purported "expert" Mr. Ahmadi arrives at his by simply multiplying "the NOL of \$916.6 million" by a "25.7% tax rate." *Id.* Mr. Ahmadi apparently assumes, among other things, that Debtors will have sufficient profit this year to utilize the entirety of the existing NOLs. Unfortunately, however, the Debtors' projections have them losing money this year and show that it would take many years to generate profits necessary to offset their NOLs. Further, he assumes that no "ownership change" will take place in that time that would decrease or eliminate Debtors' ability to utilize the NOLs under Sections 382 and 383 of the Tax Code. He also fails to discount this speculative future tax savings to account for the time value of money.

32. In other words, the NOLs have relatively little value as an asset going forward to offset a small amount of the Debtors' potential profitability. Disclosure Statement, pp. 75-78; Tax Code § 382. Moreover, the value of the NOLs has already been accounted for in the Debtors' valuation, which provides that "the Reorganized Debtors' total enterprise value does not exceed \$225 million." Disclosure Statement pp. 75, 89, Ex. F, p. 2; Aug. 7, 2020 Tr. at 62:25-63:6.

c. The Market Test Confirms The Debtors' Enterprise Valuation

33. The Debtors' financial situation has been progressively worsening for some time, despite IEH providing the Debtors opportunities to refinance the Convertible Notes, including by forbearing on them for months. Since July 2018, the Debtors have attempted to turnaround their financial performance by completing an acquisition to improve cash flow, hiring the existing management team, paying down the Secured Notes to save interest expense and seeking a refinancing of the Convertible Notes.²⁰

²⁰ April 30, 2019 Press Release accompanying 10-Q, <https://www.sec.gov/Archives/edgar/data/881524/0001104659-19-025312-index.htm> ("The first quarter of 2019 represents the completion of the third quarter of our ten-quarter turnaround. . . .").

34. The Debtors' SEC filings make clear that the Debtors had been running an equity deficit (which ranged from (\$9.3 million) to (\$69.2 million) per the 2017-2019 10-ks) and had insufficient cash (which ranged from \$30.4 million to \$66.4 million per the 2017-2019 10-ks)²¹ to pay the Convertible Notes maturing on May 1, 2020. This message is echoed in the September 2019 presentation Mr. Dijkstra attaches to his Objection, which demonstrates that the restructuring of the Debtors' debt was necessary for the company to perform, and provides four possible solutions, all of which the Debtors attempted, but failed, as the market was not willing to bear the cost and risk of the restructuring based on the Debtors' financial position. Dijkstra Obj. p. 28. That very same presentation also shows that even a year ago, the Debtors had an enterprise value consistent with their current valuation, and a negative equity value. *Id.* p. 32.

35. Most tellingly, Piper Sandler went to market to raise debt and equity capital for the Debtors three times, approaching dozens of potential parties. The most they were able to obtain was an uncommitted \$197 million, *i.e.* below the Debtors' own valuation that the Shareholder Objections argue is too low.²²

d. Mr. Makosky's "Expert" Reza Ahmadi Is Not Qualified to Offer an Opinion on Valuation and His Calculations Are Unsupportable

36. Mr. Makosky's objection consists almost entirely of a letter and accompanying CV from Reza Ahmadi, whom Mr. Makosky describes as a "financial expert," purporting to value VI-0106 and the NOLs. Under Federal Rule of Evidence 702 and the Supreme Court's *Daubert* standard, an expert opinion must have "a reliable basis in the knowledge and experience of [the

²¹ 2017 10-k p. 90, <https://www.sec.gov/Archives/edgar/data/881524/000155837018002019/0001558370-18-002019-index.htm>; 2018 10-K p. 92, <https://www.sec.gov/Archives/edgar/data/881524/000155837019001077/0001558370-19-001077-index.htm>; 2019 10-K p. 96, <https://www.sec.gov/Archives/edgar/data/881524/000155837020001956/0001558370-20-001956-index.htm>.

²² See *In re Hechinger Investment Co. of Del.*, 327 B.R. 537, 548 (D. Del. 2005) ("because valuation is, to a great extent, a subjective exercise dependent upon the input of both facts and assumptions, the court will give deference to 'prevailing marketplace values', rather than to values created with the benefit of hindsight for the purpose of litigation.").

expert's] discipline." *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 591-92 (1993); *see also* FRE 702(c), (d). According to Mr. Ahmadi's own CV, he has no such basis. Mr. Ahmadi acknowledges that his knowledge and experience are not in valuation, but "Operations Management" and "[s]pecifically . . . : 1) Scheduling and Production Planning, 2) Product and Process Design, 3) Service and Entertainment, and 4) Supply Chain Management."²³ Makosky Obj. p. 7. Yet Mr. Ahmadi purports to value with some certainty VI-0106 and the NOLs without utilizing any recognized valuation methodologies. Mr. Ahmadi's purported valuation should be disregarded on this basis alone.

37. Moreover, as noted above, Mr. Ahmadi's analysis of the value of VI-0106 provides no meaningful reasoning for his statement that "VI-0106 has present value of at least \$84.5 million, and a value of about \$1.2 billion, following successful completion of phase 2 trials within a year." Makosky Obj. p. 10. It compares the Debtors' situation to two non-analogous situations (those of Mannkind and Arena) without the application of any recognized valuation methodology approved by this Court or any other court. Mr. Ahmadi's analysis of the NOLs suffers from similar failings. It assumes that the Debtors will have sufficient profit this year to utilize the entirety of the existing NOLs and that no "ownership change" will take place, and fails to discount for the time value of money.

38. Crucially, Mr. Ahmadi's opinion is not only unsupported and outside of his knowledge and experience, it is purely speculative and as such, should be disregarded on this basis as well. *In re Spansion*, 421 B.R. at 163; *In re Ampex Corp.*, 2008 WL 2051128, at *2.

ii. The Plan Is Fair and Equitable to Shareholders

39. The Plan provides up to a \$2.28 per share recovery to shareholders. Accordingly,

²³ The Debtors do not manufacture their own drugs, so much of Mr. Ahmadi's "operations management" experience is inapplicable even to the Debtors' operations, let alone their valuation.

the potential recovery to shareholders is over \$40 million, with a minimum recovery of up to \$5 million.²⁴ The Debtors negotiated in earnest to obtain this recovery for shareholders, and IEH agreed to it, to facilitate a consensual restructuring.

40. No action need be taken to receive a recovery. This construct was a conscious one. The Debtors wanted to allow shareholders the maximum recovery (and possibility of recovery) given a presumed lack of familiarity with bankruptcy. It was the Debtors' expectation that shareholders may not understand or properly execute upon the steps needed if action were required, thereby precluding their recovery (for example, the Debtors believed few shareholders would respond to an opt-in structure -- similar to the low response rate that is frequent in class action settlements).

41. The Shareholder Objections portray IEH as having masterminded a scheme to acquire the Debtors. For his part, Mr. Dijkstra asserts that this is the cause of the prepackaged nature of the Plan. Dijkstra Obj. p. 5. There is no truth in this assertion. As Vivus Director Thomas B. King noted in his declaration, the Plan was heavily negotiated to "maximize the value of the Debtors' Estate for all the Debtors' stakeholders (including the existing equity holders)" by, among other things, providing "a meaningful recovery for equity holders, notwithstanding the fact that the Valuation Analysis illustrates the Company is insolvent." *See* King. Dec. (Docket No. 130) ¶¶ 17-19.

42. Clearly the Debtors' restructuring is not the result of a zealous noteholder, instead it is borne of necessity after the Debtors were unable to refinance, as shown by:

- a. IEH's waiting 5 years to be repaid;

²⁴ The Plan provides that each participating shareholder will receive a *pro rata* portion of \$5 million and a \$2 per share contingent value right. (Plan § 5.3.) As of June 1, 2020, the Debtors had 17,867,697 shares of common stock outstanding, which when multiplied by \$2 per share is in excess of \$35 million. Adding to that \$5 million, potential recovery to shareholders exceeds \$40 million.

- b. IEH's responding to what the Debtors perceived as roadblocks to refinancing the Convertible Notes and voluntarily offering to eliminate them;
- c. IEH's permitting other noteholders to be paid to effectuate forbearance so the Debtors could then try twice again to refinance while restructuring was negotiated at their urging as a contingency;
- d. IEH being the only classified claim or shareholder entitled to a distribution that is impaired under the Plan;
- e. IEH's offering a shareholder recovery despite its own impairment; and
- f. IEH's acquisition of Secured Note Claims with the Debtors' consent to enable a prepackaged restructuring so that the Debtors' business could be less impacted through a shorter bankruptcy as they desired.

43. IEH has waited patiently for repayment for 5 years, and prepetition provided the Debtors no fewer than three opportunities to refinance their debt -- including after the maturity date of the Convertible Notes. IEH did so without seeking the payment of any fee (which is the norm for forbearances), and had even encouraged the Debtors to seek refinancing of the Convertible Notes in the fall of 2019 by offering to eliminate any perceived roadblocks for doing so (that is, IEH explicitly offered to waive certain interest payments to permit a refinancing).

44. Now, IEH has agreed to roll the Secured Notes into the Exit Facility and take a 24% haircut on the Convertible Notes (Disclosure Statement, pp. 7-8), in excess of \$40 million, which is the only reason creditors are being paid in full.

45. Moreover, there is no "death trap," as Mr. Chlavin's counsel admitted to the Court. *See* Aug. 7, 2020 Tr. at 72:18-20. Death traps entice classified stakeholders arguably entitled to a recovery to vote in favor of a plan so as to bind a dissenting minority. Here, shareholders are entitled to no recovery, are deemed to reject, and each shareholder has the right to choose whether to participate in the Existing Stock Settlement, object to confirmation, or opt-out of the third party releases and file suit. Plan, §§ 4.7 and 5.3. For this reason as well, there is no "discriminatory treatment" between shareholders. *See* Chlavin Obj. ¶¶ 11, 13.

Conclusion

WHEREFORE, IEH respectfully requests that this Court issue an order confirming the Debtors' Plan, and granting the Debtors such other and further relief as this Court deems appropriate.

Dated: August 18, 2020

COLE SCHOTZ P.C.

By: /s/ Justin R. Alberto
Justin R. Alberto (No. 5126)
Andrew Roth-Moore (No. 5988)
500 Delaware Avenue, Suite 1410
Wilmington, DE 19801
Telephone: (302) 652-3131
Facsimile: (302) 652-3117
jalberto@coleschotz.com
aroth-moore@coleschotz.com

- and -

DENTONS US LLP
Oscar N. Pinkas
Brian E. Greer
Lauren Macksoud
1221 Avenue of the Americas
New York, NY 10020
Telephone: (212) 768-6700
Facsimile: (212) 768-6800
oscar.pinkas@dentons.com
brian.greer@dentons.com
lauren.macksoud@dentons.com

Counsel to IEH Biopharma LLC